

Attorney Docket 2000-0702.ORI

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re App	: Brian Hawtin	Art Unit: 1619
Serial No	: 09/701,140	Exam: Lauren Q. Wells
Filed	: November 21, 2000	
For	: Formulation	

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DECLARATION OF BRIAN HAWTIN

The Commissioner of Patents and Trademarks

Washington, D.C. 20231

Sir:

I, Brian Hawtin, the inventor in the above-identified application for United States letters patent hereby declare as follows:

1. That I am a citizen of the United Kingdom, and a resident of Oker, Matlock, Derbyshire, UK, residing at Aston Grange, and the named inventor in the above-identified application for United States Letters Patent;
2. That I am presently employed by Venture Healthcare Limited where I hold the title of Managing Director, a position which I have held for 12 years, it being in the business of pharmaceutical preparations;
3. That I have been engaged in the development of pharmaceutical compositions for the treatment of skin-related disease and conditions for a period of at least about 37 years;
4. That in the course of these activities, I have personally become familiar with the problems encountered with transdermal transmission of pharmaceutically active drugs in topical treatments;

5. That in the course of the prosecution of the above-identified application for United States Letter Patent, I have become familiar with the subject matter of the references cited by the examiner in the course of prosecution, including the following:

British Patent Number 2,202,145

European Patent Application 0 189 861 A2

U.S. Patent No. 5,888,478

U.S. Patent No. 5,190,917

U.S. Patent No. 4,883,792

and, have related the substance of the claimed subject matter to disclosures of these references;

6. That the subject matter of these references do not provide the unexpected benefits of the presently claimed compositions, with the reasons being as follows: when compositions with and without an amphoteric surfactant and alkoxylated cetyl alcohol were compared, only compositions comprising an amphoteric surfactant and alkoxylated cetyl alcohol were found to be stable and to have the required consistency, very low skin sensitivity and good emollient properties.

Composition	Amphoteric surfactant?	Alkoxylated cetyl alcohol?	Stability	Consistency
Test 1	No	No	Unstable	Unusable
Test 2	No	No	Unstable	Unusable
Example 3	Yes	Yes	Stable	Easy to apply

"Example 3" refers to a composition as described in Example 3 of the present application. "Test 1" refers to a composition which differs from that

of Example 3 in that the amphoteric surfactant and alkoxyated cetyl alcohol are absent. "Test 2" refers to a composition which differs from that of Test 1 in that the preservative benzalkonium chloride is present in place of the preservatives triclosan and benzyl alcohol.

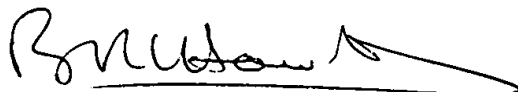
The composition of Example 3 is stable at room temperature for several weeks. The compositions Test 1 and Test 2 separate into oil and water phases after less than one week at room temperature. Compositions Test 1 and Test 2 are unusable because of their poor stability. In addition, the composition of Example 3 has better consistency, feel, and emolliency than compositions Test 1 and Test 2;

7. That based upon my education and experience, I am fully confident that the Totten et al (GB 2 202 145) reference, the Motoaki et al (EP 0 189 861) reference, and the Maurin (US 5,888,478) reference, whether taken alone or in combination, fail to teach or suggest the unexpected beneficial results of the pharmaceutical compositions embodied in the presently pending claims;

8. That this Declaration is given for the purpose of defining and delineating distinctions present in the claimed subject matter of this application from the disclosures available in the references being relied upon by examiner, and that this Declaration is given in support of the patentability of the claims presently under consideration.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on 5th SEPTEMBER, 2002.



Brian Hawtin